

Continuation of 5. Applicant's reply has overcome the following rejection(s): The rejection of claim 11 under 35 USC 112, second paragraph is withdrawn in light of the amendments. The claim no longer depends from a canceled claim. However note the claim is still rejected under 35 USC 103, see reasons included in section 11 herein.

Continuation of 11. does NOT place the application in condition for allowance because: The rejections under 35 USC 102 and 103 are maintained for the reasons of record.

Claims 1, 3-4, 6-9, and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura (EP 0456188A1, of record). Applicant argues that the rejection under 35 USC 102 is improper because the Nakamura reference does not teach compositions comprising one of the stabilizing agents recited in claim 1 and sodium chloride and a buffering agent. Applicant also argues that the examiner is picking and choosing between unrelated parts of the reference which is not proper for a rejection under §102, and cites the non-precedential Board decision Ex parte Bobsein and the CCPA decision In re Arkley in support. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that the non-final office action referred to Example 1, which appears at column 14 line 25, and clearly teaches a composition comprising 0.02 M phosphate buffer, 0.15 M NaCl, and HGF. 1 mg of HGF is added to 100 ml of solution; the starting concentration is thus lower than 5 mg per ml; it is 0.01 mg per ml. The composition is lyophilized. The examiner concedes that this single paragraph does not include arginine, the elected species.

However, the remainder of the reference clearly does teach the claimed invention. On p. 4, final paragraph, of the Final Rejection mailed 16 February 2006, the examiner directed applicant's attention to the paragraph spanning columns 9 - 10 of the Nakamura reference in support of the rejection under 35 USC 102. These paragraphs, along with the paragraph immediately preceding it, clearly teach every limitation of the claimed invention. At this point, the reference discusses preparation of HGF suitable for injection. The reference clearly teaches that injections are to be prepared with HGF "solely or combinedly with carriers etc" (column 9 lines 45 - 47). The reference teaches that injections "can be prepared by dissolving in suitable buffers" (col. 9 lines 49 - 50). There is no question that the reference teaches a composition comprising HGF and a buffer. What follows is a very detailed showing of how the reference, in this one single passage, teaches the remainder of the invention as well.

The very next paragraph, the paragraph which spans columns 9 to 10, teaches that "the therapeutic agents... may contain other additives such as stabilizers, excipients, dissolution promoters, adsorption preventors and antioxidants". In this text, Nakamura is clearly contemplating the addition of many different components. Applicant is reminded that in the paragraph beginning at column 9 line 45 Nakamura specifically said that the "carriers etc" can be combined. Nakamura teaches the addition of arginine (column 9 last line). Nakamura teaches the addition of "inorganic salts such as NaCl" (column 10 line 3). NaCl is sodium chloride. Nakamura ends this paragraph by reminding the reader that the agents which have just been described "may be used alone or in combination." (column 10 line 6). Because Nakamura teaches all the components of the now-claimed composition, and teaches that they can all be added, to injections comprising HGF, the reference teaches the entire composition recited in claim 1. Up to this point, however, the reference has not yet taught lyophilizing the composition.

However, the very next paragraph (column 10, lines 7 - 13) tells the artisan to lyophilize the preparation. The reference uses the terms "vacuum drying" and "freeze drying". Lyophilization is a process of vacuum-drying a solution in the presence of a vacuum. Clearly the reference teaches the lyophilized preparation as recited in claim 1.

The final clause of claim 1, "which is prepared from" is a product-by-process limitation. The examiner concedes that this text of the reference does not teach the exact starting concentration of HGF used. However, applicant is not claiming the method, applicant is claiming the product made by this method. The product now claimed is identical to that taught by Nakamura.

On page 11 of the remarks, applicant respectfully disagrees with the examiner's contention that arginine, as taught by Nakamura, is a stabilizing agent. Applicant's arguments have been fully considered but they are not persuasive. First, the examiner notes that Nakamura lists arginine in the same sentence as "stabilizers". It appears that Nakamura contemplated that arginine had stabilizing properties. However, whether or not Nakamura's intended use of the arginine was as a stabilizing agent is immaterial. Instant claim 1 recites "a stabilizing agent comprising arginine... for preventing formation of an aggregate...". The intended use or purpose of arginine is immaterial, as Nakamura clearly teaches a composition which is now claimed.

For the reason stated above, Nakamura clearly anticipates claim 1. The examiner now turns applicant's attention to claims 3 - 4, 6 - 9, and 12 - 15. Claim 3 recites the same composition as claim 1. It also requires that the composition be capable of being reconstituted at less than 5 mg/ml. This is an inherent property of the composition. It can be reconstituted at less than 5 mg per ml; all one has to do is add sufficient water and one could have essentially any concentration, although the maximum possible concentration would be expected to be limited by the physical properties of the agents of the composition. Claim 4 recites "wherein the stabilizing agent comprises arginine...". As explained above, the paragraph spanning columns 9 - 10 of Nakamura teaches addition of arginine. Claim 6 is very similar, although glutamic acid is not recited and the newly-added limitation "comprising" has been added. However, since the reference teaches the addition of arginine, it also meets the limitations of claim 6. The examiner notes that "comprising" allows for, but does not require, the addition of other elements not recited in the claim. As the prior art reference teaches addition of arginine, which is a stabilizing agent, in the composition, it clearly meets the limitation of the claim.

Claim 7 limits the buffering agent to a phosphoric acid salt. For the sake of brevity, Nakamura did not list all possible buffers when he listed the stabilizing agents. He did, however, teach the artisan to dissolve HGF "in suitable buffers" (column 9 line 50). Elsewhere throughout the reference, including at Examples 1 and 2 (column 14 lines 25 - 45), Nakamura specifically teaches inclusion of phosphate buffer. Thus these later examples provide evidence that Nakamura considered phosphate buffer, which is a phosphoric acid salt, to be a member of the genus of suitable buffers. This is not an instance of the examiner picking and choosing among various parts of the reference to improperly construct a rejection under § 102, rather, the examiner is using one part of the disclosure as supporting evidence for another part of the disclosure.

Claims 8 - 9 are drawn to inherent properties of the product before lyophilization and after dissolution. The reference is silent as to the actual pH of the composition taught on columns 9 - 10. However, after setting forth a prima facie case of inherency, the burden shifts